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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------|-------------------|----------------------|-------------------------|-------------------------------|--|
| 09/685,940 | 10/10/2000 | Shi Kun Huang | 5325-0166.30 | 6690 | |
| 759 | 02/20/2002 | | | • | |
| Paul B. Simbol | = - | | EXAM | EXAMINER KISHORE, GOLLAMUDI S | |
| P.O. Box 7210 | Road, Bldg. M10-3 | | KISHORE, GO | | |
| Mountain View, | CA 94039-7210 | | ART UNIT | PAPER NUMBER | |
| | | | 1615 | | |
| | | | DATE MAILED: 02/20/2002 | DATE MAILED: 02/20/2002 | |

Please find below and/or attached an Office communication concerning this application or proceeding.



Office Action Summary

Application No. 09/685,940 Applicant(s)

Gollamudi S. Kishore, Ph.D

Art Unit 1615

Huang



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30 days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

| Any reply received by the Office earned patent term adjustmen | | the mailing date of this communication, even if timely filed, may reduce any | | | |
|--|---|---|--|--|--|
| Status | | | | | |
| 1) Responsive to commun | Responsive to communication(s) filed on | | | | |
| 2a) This action is FINAL . | This action is FINAL . 2b) This action is non-final. | | | | |
| The state of the s | | ce except for formal matters, prosecution as to the merits is parte Quayle, 1935 C.D. 11; 453 O.G. 213. | | | |
| Disposition of Claims | | | | | |
| 4) 💢 Claim(s) <u>1-33</u> | · | is/are pending in the application. | | | |
| 4a) Of the above, claim(| s) | is/are withdrawn from consideration | | | |
| 5) | | is/are allowed. | | | |
| 6) Claim(s) | | is/are rejected. | | | |
| | | is/are objected to. | | | |
| | | are subject to restriction and/or election requiremen | | | |
| | correction filed on | are objected to by the Examiner is: a) ☐ approved b) ☐ disapproved. | | | |
| riority under 35 U.S.C. § 119 | nade of a claim for foreign | n priority under 35 U.S.C. § 119(a)-(d). | | | |
| | f the priority documents h | nave been received. | | | |
| _ | | nave been received in Application No | | | |
| application | i from the International Bu | y documents have been received in this National Stage ureau (PCT Rule 17.2(a)). the certified copies not received. | | | |
| 4) Acknowledgement is m | ade of a claim for domest | stic priority under 35 U.S.C. § 119(e). | | | |
| ttachment(s) | | | | | |
| 5) Notice of References Cited (PTO-892 | 2) | 18) Interview Summary (PTO-413) Paper No(s). | | | |
| B) Notice of Draftsperson's Patent Draw | ring Review (PTO-948) | 19) Notice of Informal Patent Application (PTO-152) | | | |
| 7) Information Disclosure Statement(s) (| PTO-1449) Paper No(s) | 20) Other: | | | |

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DETAILED ACTION

Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-18, 28-32 are, drawn to liposome compositions and a method of treatment, classified in class 424, subclass 450.
 - II. Claims 19-27 are, drawn to lipid compounds, classified in class 554, subclass1 plus.
- 2. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as drug carriers in micellar or emulsion forms and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the

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inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
- 4. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.
- 5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 6. This application contains claims directed to the following patentably distinct species of the claimed invention: a) where L is carbamate; b) ester; c) carbonate.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1 and 19 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is

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allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

Gollamudi S. Kishore, Ph. D

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Primary Examiner

Group 1600

gsk

February 13, 2002